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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,553	04/09/2004	John Morley	0701.079H	4834

7590 09/27/2004
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EXAMINER

COOK, REBECCA

ART UNIT PAPER NUMBER

1614

DATE MAILED: 09/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/821,553

Applicant(s)

MORLEY, JOHN

Examiner

Rebecca Cook

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/9/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borgstrom et al (AX) in view of Ariens (originally cited by examiner) and further in view of Koshino et al (AR6).

Borgstrom et al (page 49, column 1, lines 1-3) disclose that it is well-known to use terbutaline to treat obstructive airway disease. Borgstrom et al (page 40, column 1, lines 8-11) further disclose that the (-) enantiomer is the active form of the compound and that the (+) enantiomer is devoid of agonist activity. The claims differ over the reference in requiring the use of 98% of the R-enantiomer in order to avoid, ameliorate or restrict the deleterious side effects caused by the inactive enantiomer. Dependent claim 14 further requires the use of ketotifen. Claim 15 recites an inhalable terbutaline pulmonary composition comprising greater than 98% R-terbutaline.

However, Ariens (abstract, lines 4-5, page 200, column 3, lines 24-29, page 202, columns 1-3) discloses that the inactive enantiomer of drugs may be responsible for undesirable side effects. Furthermore, Koshino et al (page 1224, line 6, through page 1225, line 9, page 1226, lines 19-22) disclose that ketotifen may be used in combination with other .beta.-agonist drugs.

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It would be obvious to one of ordinary skill in the art that using the predominantly bronchodilator enantiomer form of terbutaline would avoid, ameliorate or restrict the occurrence of deleterious side effects caused by the inactive bronchodilator enantiomer. That is because Ariens discloses that the inactive enantiomer of drugs is responsible for undesirable side effects and Borgstrom et al disclose that one enantiomer of terbutaline is the active form of the compounds. One would be motivated to do so by the desire to treat obstructive airway disease with the enantiomer known for said treatment and to avoid the undesirable side effects that the inactive enantiomer is associated with.

Furthermore, it is well known to administer a bronchodilator drug via the pulmonary route. Additionally, it would be obvious to combine terbutaline and ketotifen, since both compounds are well known to be useful to treat obstructive airway disease. One would be motivated to use the instant method and composition by the desire to have a useful method and composition to treat airway disease.

Cited References

The references have not been provided, since they were cited and provided in parent application 10/095,846.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (571) 272-0571. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Renee Jones (571) 272-0547 in Customer Service.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The official fax number is 703-872-9806

Rebecca Cook

A handwritten signature in black ink, appearing to read 'Rebecca Cook', written in a cursive style.

Primary Examiner
Art Unit 1614

September 23, 2004